Effects of a six-week exercise intervention on function, pain and lumbar multifidus muscle cross-sectional area in chronic low back pain: A proof-of-concept study

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Abstract

Introduction: Exercise with the Functional Re-adaptive Exercise Device (FRED) has previously been shown to activate the lumbar multifidus (LM) and transversus abdominis (TrA) muscles in non-symptomatic volunteers. This study aimed to determine the effects of a six-week FRED exercise intervention on pain intensity, patient-reported function and LM cross sectional area (CSA) in people with chronic non-specific low back pain (LBP).

Methods: Thirteen participants undertook six weeks of FRED exercise for up to 15 minutes, three times per week. At six weeks pre-, immediately pre-, immediately post-, and six and 15 weeks post-intervention, participants completed the Numeric Pain Rating Scale, Patient-Specific Functional Scale, and ultrasound imaging was used to assess the size of the LM

muscles at L5 level. Changes in outcomes were assessed using effect size, confidence intervals and minimum clinically important difference (MCID).

Results: There was no improvement in pain intensity following the intervention. Patient-reported function improved by at least twice the MCID for all follow-up assessments compared to immediately pre-intervention (d = 4.20-6.58). Lumbar multifidus CSA showed a large effect size increase from immediately pre-intervention to immediately post-intervention (d=0.8-1.1); this was maintained at six weeks post-intervention (not measured at 15 weeks post-intervention).

Conclusion: Six weeks of FRED exercise improved physical function in all 13 participants with chronic non-specific LBP who took part in this study and most participants' lumbar multifidus muscle CSA. On this basis, it may be an effective intervention for people with chronic LBP and should now be tested in a randomised controlled trial.

Keywords: chronic low back pain, exercise, physical function, lumbar multifidus muscle, motor control.

INTRODUCTION AND BACKGROUND

Low back pain (LBP) is a serious drain on health resources worldwide (Hoy et al., 2012; Kaplan et al., 2013) and involves a complex interplay of biomechanical, physiological and psychosocial factors. Chronic LBP not only makes an important contribution to these figures, it results in considerable limitations for those affected and their families. People with chronic LBP identified that it impacted on their ability to engage in physical activities, family life, and social and re-creational activities (Turk et al., 2008).

Exercise is widely recognised as an effective treatment for chronic LBP (Airaksinen, Brox, Cedraschi, & et al., 2006; Ferreira, Ferreira, Maher, & et al., 2006; Koes, van Tulder, Lin, & et

al., 2010), but the form of exercise used varies greatly. The Motor Control Training (MCT) approach is an evidence-based approach to treating LBP (Macedo, Maher, Latimer, & McAuley, 2009; Saragiotto et al., 2016). MCT aims to identify the features of motor control of the lumbopelvic region, including muscle activation (including the the deep abdominal and paraspinal muscles), posture and movement that are considered to suboptimally load the spine and contribute to ongoing nociceptive input, which may be relevant for ongoing pain in many but not all individuals with LBP (Hodges et al., 2013; Hodges, 2019). Training involves modification of the indentified features and progression into fully integrated functional movement (Hodges et al., 2013).

A muscle that is frequently considered in this context is the lumbar multifidus (LM). This attention is based on the link between atrophy (e.g. Hodges & Moseley, 2003; Hodges, Holm, Hansson, & Holm, 2006) and dysfunction (e.g. MacDonald, Moseley, & Hodges, 2009; Tsao, Druitt, Schollum, & Hodges, 2010; Wallwork, Stanton, Freke, & Hides, 2009) of this muscle and LBP. These structural and functional changes in LM muscle are argued to be relevant for many with LBP because of the role of this muscle in inter-vertrebral segmental control (Hodges & Moseley, 2003; MacDonald, Moseley, & Hodges, 2006), control of the lumbar lordosis (Claus, Hides, Moseley, & Hodges, 2009; Moseley, Hodges, & Gandevia, 2002), and proprioception (Brumagne, Lysens, Swinnen, & Verschueren, 1999; Brumagne, Janssens, Claeys, & Pijnnburg, 2013; Claeys, Brumagne, Dankaerts, Kiers, & Janssens, 2011). In functions that require ongoing postural support, it would be expected that the LM would be active in a tonic rather than phasic manner (Dickx et al., 2010; Jull & Richardson, 2000; MacDonald et al., 2006). For these reasons, in many exercise-based approaches, including MCT, restoring LM function and muscle mass are considered to be key targets for rehabilitation of many people with LBP. However, many physiotherapists observe that their patients have difficulty recruiting LM voluntarily without biofeedback using ultrasound imaging (Whittaker, 2007). This presents a challenge in clinical practice.

A novel exercise device involves a cyclical 'walking-type' movement in an upright standing position and without the use of upper limbs for support. Users work against virtually no external resistance which means that they have to actively control the descent of the front leg and the elevation of the rear leg throughout each movement cycle while maintaining an upright standing position on an unstable base of support. When using the Functional Re-adaptive Exercise Device (FRED) (Figure 1), the LM muscle is activated with greater magnitude (as apparent from ultrasound imaging) than during a range of test conditions, including standing on level ground and on an unstable base of support, and a voluntary contraction of the LM muscle in non-symptomatic volunteers (Debuse, Birch, St Clair Gibson, & Caplan, 2013). A single session of exercise on the FRED also induces a lumbar lordosis angle that O'Sullivan et al., (2006) and Roussouly, Gollogly, Berthonnaud and Dimnet (2005) argued is favourable for the activation of LM (Winnard, Debuse, Wilkinson, Tahmosybayat, & Caplan, 2017). And it activates the lumbo-pelvic muscles in a more tonic manner than during walking on a treadmill (Caplan, Gibbon, Hibbs, Evetts, & Debuse, 2014; Weber et al., 2017). As these findings indicate that FRED exercise activates the LM muscle in several of its 'functions', FRED exercise may be useful in the rehabilitation of people with LBP (Caplan et al., 2014).

The effects of FRED exercise as an intervention in a symptomatic population have not been investigated. The aims of this proof-of-concept study were first, to examine the effects of a six-week FRED exercise intervention on pain and function in a group of individuals with chronic non-specific LBP, and second, to investigate the impact of the intervention on the muscular impairment that the intervention is purported to address, that is, LM muscle cross sectional area (CSA).

Figure 1: The Functional Re-adaptive Exercise Device

METHODS

Sampling and recruitment

Participants were recruited from the lead (academic) institution's staff and research student population, and their families and friends via emails, posters and at a "fitness at work" event at which potential participants had the opportunity to exercise on the FRED. Those who met the inclusion/exclusion criteria (Table 1) were invited for an initial physiotherapy screening assessment (Figure 2). Data collection took place in the Movement Laboratory of the lead institution.

Initial screening was performed by a Chartered Physiotherapist with considerable experience in the examination and management of patients with chronic LBP (DD). The purpose was to screen out potential candidates with suspected serious pathologies who would have to be referred on for further investigations and to identify participants with chronic non-specific LBP. As LM atrophy (Wallwork et al., 2009; Fortyn & Macedo, 2013; Hides, Stanton, McMahon, Sims, & Richardson, 2008) and dysfunction (Hides, Stanton, Mendis, & Sexton, 2011; Wallwork et al., 2009) have been identified frequently in LBP, and was a major target for the FRED intervention, LM muscle dysfunction was assessed via palpation of the muscle during a voluntary contraction, using the "LM swelling technique" described by Hides, Richardson and Hodges (1989, p. 194-197). In this proof-of-concept study we elected to only include participants who had difficulty activating the muscle voluntarily as clinical evidence of dysfunction of this muscle. This was undertaken as our interest was to first evaluate whether the intervention would be successful in the subset of individuals who had a presumed dysfunction of the muscle.

Potential participants were also screened to ensure they were able to exercise safely on the FRED in standing without holding on to the frame and without risk of losing balance. A sample of 14 (7 female, 7 male) participants with chronic LBP was recruited to this study. An overview of their characteristics is presented in Table 2.

Inclusion criteria:	Exclusion criteria:
• 12 weeks or longer history of LBP • Age 18-65 years • Difficulty activating the LM muscle as clinical evidence of dysfunction of this muscle • Minimum pain level of 4 out of 10 on the Numerical Pain Rating Scale (NPRS) • Sufficient balance to exercise safely on the FRED (i.e. without holding on to the frame during exercise) • Willingness to take part in the study for its full duration	• Presence of "red flags" – indicative of the possibility of a serious pathology that would require further investigation • Score of >15 on FABQ indicating a likely poor response to a *solely* physical approach to LBP • Exercise contraindicated as per Physical Activity Readiness Questionnaire • Pregnancy • Other pain unrelated to LBP that may affect FRED exercise performance or engagement • Surgery to the torso or lower limbs within the previous nine months • Difficulty to exercise safely in standing for 20 mins 3x/week • Major cardiovascular/respiratory disease • Neurological disorders • BMI >30 (excess adipose tissue impairs clarity of US imaging of the LM muscle)

Table 1: Inclusion/Exclusion Criteria

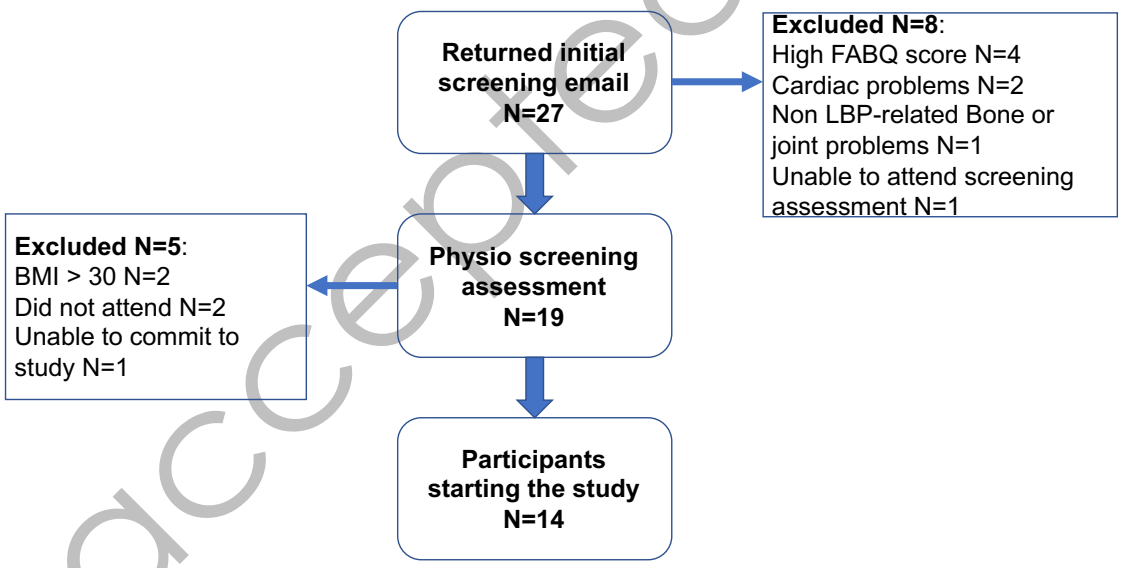

Figure 2: Participant recruitment/screening

Participant Number	Age	Height	Body weight	BMI	Duration of symptoms (years)	Location of LBP	Leg pain
1	41	1.69	86	30	28	central	no
2	33	1.84	77	22.7	5	central	no
3	35	1.71	55	18.8	3	Right	no
4	56	1.73	81	27.1	14	central	no
5	59	1.81	95	29	1	central	left
6	55	1.71	65	22.2	0.5	central	no
7	53	1.67	60	21.5	17	central	no
8	51	1.93	96	25.8	19	central	right
9	43	1.73	79	26.4	0.75	central	no
11	53	1.67	77	27.6	35	central	no
12	53	1.59	67	26.5	40	central	no
13	29	1.70	61	21.1	5	Left	no
14	38	1.80	75	23.1	15	Right	no
mean ± SD	**46 ± 9 years**	**1.73 ± 0.08 m**	**75 ± 12 kg**	**22.9 ± 3.6 kg.m^2**	**14 ± 13 years**		
range	**29-59 years**	**1.59-1.93m**	**55-96kg**	**18.8-30**	**0.5-40 years**		

Table 2: Participant characteristics (Participant 10 withdrew prior to data collection)

The study received ethical approval from the Institutional Review Board and the European Space Agency Medical Board, and complied with the Declaration of Helsinki. All participants gave their written informed consent to take part. The study was registered with ClinicalTrials.gov, number NCT03062293.

Study design

The study was a non-randomised, non-controlled, single-blind proof-of-concept study and used a repeated measures design. Change in all participants was assessed at the same time points over a period of time, and all particpants underwent the same intervention. The stability of participants' presentation was assessed at baseline with two assessments performed 6 weeks apart prior to commencement of the intervention. The study was conducted over 29 weeks, with the intervention provided over six weeks (Figure 3). This study design enabled examination of any potential changes in measures during periods without the intervention (both before and after the intervention period), and observation of the longer-term effects of the intervention.

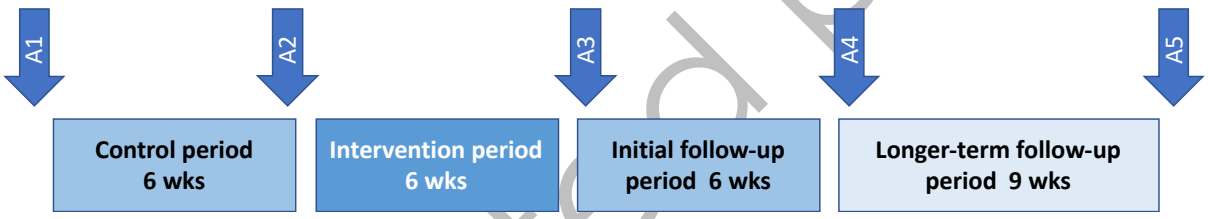

Figure 3: The study time-course (A = assessment)

Throughout all periods of the study, participants continued with all their usual activities including hobbies and sports, medication, and work. This made the study 'real life' in that participants did not need to change any of their normal behaviours for the study, other than having to make time to attend the exercise sessions three times per week during the intervention period.

Assessment

Assessments of outcomes were made at multiple time points (Figure 3) using the following outcome measures: the 11-point Numeric Pain Rating Scale (NPRS) of average pain over the past week, anchored with “no pain” at 0 and “worst pain imaginable” at 10 (Farrar, Young, LaMoreaux, Werth, & Poole, 2001), the Patient-Specific Functional Scale (PSFS) (Abbott &

Schmitt, 2014; Horn et al., 2012; Barten, Pisters, Huisman, Takken, & Veenhof, 2012) and CSA of the LM muscle assessed with ultrasound imaging (Hides et al., 2008a). NPRS, PSFS and LM CSA were assessed at Assessments 1-4. At Assessment 5, only PSFS and NPRS data were collected.

The PSFS provides an individualised assessment of patients‘ perceived functional capacity and is a commonly used outcome in studies of musculoskeletal pain (e.g. Sterling et al., 2007). Participants self-identified functional activities which they found difficult or impossible to do at the point of assessment. A score of 0 represented an inability to complete the task for a defined period, for example ‘standing for 20 minutes pain free’, and a score of 10 represented being able to complete the task as if the participant had no limitation. The same tasks nominated in the initial assessment were used in the follow-up assessments. For analysis, activities were grouped into “standing”, “sitting”, “bending/twisting”, or “physically demanding” activities.

As a major goal of FRED exercise is to improve muscular control of the spine, measurement of assessment of LM CSA was included to evaluate whether the dosage of FRED programme investigated here was sufficient to change this aspect of LM structure. Ultrasound images of LM muscle CSA were collected using an Esaote Tecnos MP T7500 (Italy) ultrasound machine with a 5-7 MHz curvilinear transducer, set to 7 MHz for all images. Ultrasound imaging was conducted by a single researcher (KL) who had received research-specific training on lumbo-pelvic imaging techniques. Intra-rater $ICC_{3,1}$ scores for this researcher were good (0.845). The LM muscle was imaged bilaterally in cross-section at the level of L5 with participants lying at rest in prone (Stokes, Rankin, & Newham, 2005) with their legs straight (with a pillow under their ankles for comfort) and their arms by their side. Excessive lumbar curvature was reduced using a pillow under the participant's stomach. Lumbar lordosis was eyeballed by the Chartered Physiotherapist taking the ultrasound images. Participant comfort was also taken into account. At least three images on each side were recorded at end-exhalation (Teyhen & Koppenhaver, 2011).

Intervention

This was the first study to use FRED exercise as an intervention in a symptomatic population. In the absence of previous published data to determine dosage, the selected dosage was selected to challenge participants but enable them to maintain quality performance of the task. FRED exercise involves real-time feedback of variability of movement of the foot plates of the FRED (Winnard, Debuse, Wilkinson, Tahmosybayat, et al., 2017). Our preliminary experience with the device indicated that 15 minutes of training, 3 times per week, would be achievable by most participants and this was selected as the dosage used in this study to standardise the exercise exposure. Participants' exercise took place in the university movement laboratory which participants knew from data collection and was supervised by a Chartered Physiotherapist (KL). Participants were encouraged to exercise at a slow steady pace and to focus on maintaining an even speed of movement throughout each cycle of movement. To optimise exercise performance, real-time visual feedback of variability of the foot plate movement was provided on a screen at participants' eye level. Participants were coached to ensure they did not exercise beyond their individual point of tiring and to ensure good exercise technique as determined by low variability of (footplate movement) speed throughout each cycle of movement. They all started at the smallest amplitude (0.2m) and were progressed to a larger FRED amplitude setting to increase demand (Winnard, Debuse, Wilkinson, Samson, et al., 2017) once they achieved a 30% improvement in movement variability from their baseline, and based on their clinical presentation (e.g. fatigue, leg discomfort).

Ultrasound image analysis

LM CSA was measured from ultrasound images using ImageJ software (National Institutes of Health, MD; available from https://imagej.nih.gov/ij/) by one researcher (KL), who was blinded to both participant number and time point at which each image was taken by an independent researcher (AW) in order to limit potential for bias. LM CSA was measured by tracing the inner edge of the muscle border. The means ± SD of nine measurements from three images were calculated, as well as the mean difference between assessment points.

Statistical analysis

In line with the recommendations on the use of statistical tests for intervention studies (Button et al., 2013; Hopkins, Marshall, Batterham, & Hanin, 2009; Hurst & Bolton, 2004; Wilkinson, 2014), the effect of the treatment was assessed by comparison of change relative to minimum clinically important difference (MCID) rather than statistical significance testing. Where MCID was not known, the effect size (ES), and 95% confidence intervals (Brandstätter, 1999) were used to examine the effects of the intervention. Cohen's d ES (Cohen, 1988) were calculated for each pairwise comparison of each outcome, with <0.2 indicating a trivial effect, <0.5 indicating a small effect, <0.8 indicating a moderate effect and >0.8 a large effect. For the PSFS, a MCID of 2 has been proposed for chronic LBP in a systematic review by Horn et al. (2012). The NPRS outcomes were analysed according to an MCID of 2 for patients with chronic LBP (Salaffi, Stancati, Silvestri, Ciapetti, & Grassi, 2004).

RESULTS

One participant withdrew from the study after Assessment 1 due to time constraints. Thus, 13 participants completed the intervention and are included in the analyses. None of the participants had ever had previous surgery to the torso.

Pain did not improve with the intervention (Table 3). It was also the only outcome which showed an improvement, though not a clinically important difference, over the duration of the control period (pre-intervention).

NPRS	Comparison	Δ Mean	95% CIs		ES	(Multiples of) MCID
			Lower	Upper		
Pain	A1 to A2	-3	-5	-1	-1.2	Not applicable
	A2 to A3	0	-2	1	0.3	
	A2 to A4	-1	-2	1	0.1	
	A2 to A5	-1	-3	0	0.1	

Table 3: Mean difference, 95% confidence intervals (CIs), and Cohen's d effect sizes (ES) and (multiples of) minimal clinically important difference (MCID) for the Numeric Pain Rating Scale (NPRS) outcomes

Changes in PSFS are reported in Table 4 and Figure 4. All post-intervention increases in PSFS were at least twice the MCID, increases in PSFS standing activities were more than three times the MCID. These improvements were maintained at follow-up six and 15 weeks post-intervention.

PSFS	Comparison	Δ Mean	95% Confidence Intervals		Cohen's d ES	Multiples of MCID
			Lower	Upper		
Standing activities	A1 to A2	0.25	-0.26	0.86	1.3 large	0
	A2 to A3	6.25*	2.74	10.86	4.1 large	>3
	A2 to A4	6.58*	3.62	10.78	4.6 large	>3
	A2 to A5	6.58*	4.09	10.51	4.6 large	>3
Sitting activities	A1 to A2	1.33	-0.93	3.60	1.4 large	0
	A2 to A3	5.33*	2.79	7.88	3.3 large	>2.5
	A2 to A4	5.58*	3.32	7.84	3.3 large	>2.5
	A2 to A5	5.42*	3.01	7.82	2.4 large	>2.5
Bending, lifting and twisting activities	A1 to A2	1.00	0.08	1.92	2.2 large	0
	A2 to A3	5.00*	3.15	6.85	4.1 large	2.5
	A2 to A4	5.61*	3.53	7.68	3.7 large	>2.5
	A2 to A5	6.21*	4.05	8.38	5.1 large	>3
Physical activities (e.g. walking, running)	A1 to A2	1.75	-1.03	3.86	0.9 large	0
	A2 to A3	4.20*	-0.44	4.77	1.6 large	>2
	A2 to A4	5.22*	-0.53	5.58	2.1 large	>2.5
	A2 to A5	4.79*	-0.84	3.86	1.8 large	>2

Table 4: Mean difference, 95% confidence intervals (CIs), Cohen's d effect sizes (ES) and (multiples of) minimal clinically important difference (MCID) for the Patient Specific Functional Scale (PSFS) outcomes - * denotes multiples of MCID > 2

LM muscle CSA data are reported in Table 5. Analysis showed that LM CSA at A1 was smaller (male mean 5.22 cm^2, SD: 2.11, ES 1.8; female mean: 4.77 cm^2, SD: 1.92, ES 1.3) than the reference range (male mean: 8.91 cm^2, SD: 1.68, female mean: 6.65 cm^2, SD: 1) for data that have previously been reported for non-symptomatic individuals with a mostly sedentary or moderately active lifestyle (Stokes et al., 2005). Consistent with our intention to include individuals with LM dysfunction as baseline, this would indicate that LM CSA was smaller than expected at the beginning of the study. All post-intervention increases in CSA had a large effect size (0.8-1.1). The improvement was maintained at follow-up six weeks post-intervention (this outcome was not assessed at 15 weeks).

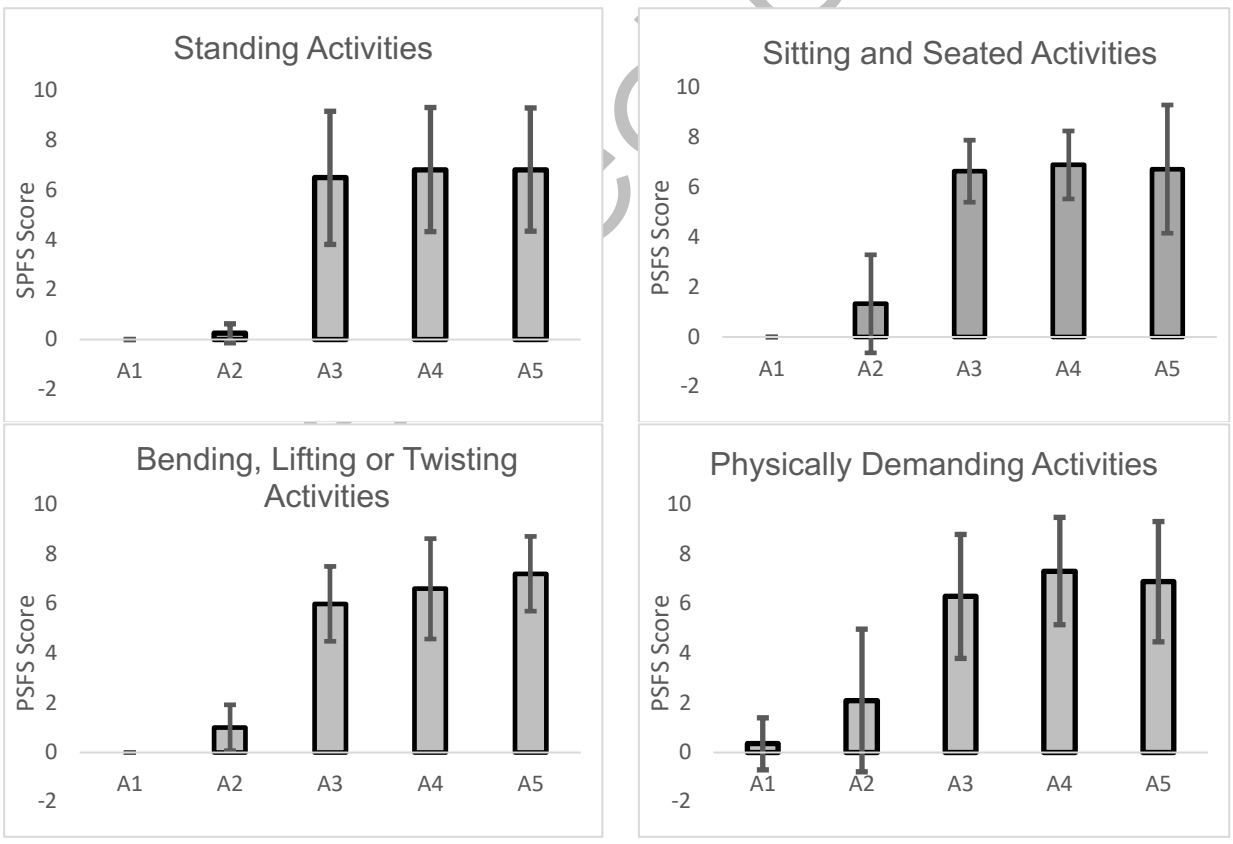

Figure 4: Participants' patient specific functional scale (PSFS) scores. Mean (±SD) shown at each assessment point. A1 - six weeks pre intervention; A2 - immediately pre-intervention; A3 - immediately post-intervention; A4 - six weeks post-intervention; A5 - 15 weeks post-intervention.

Variable	Comparison	Δ Mean (cm^2)	95% CIs		ES
			Lower	Upper	
Left LM muscle CSA	A1 to A2	0.26	-0.20	0.73	0.31 small
	A2 to A3	1	0.52	1.48	1.1 large
	A2 to A4	0.87	0.12	1.62	1 large
Right LM muscle CSA	A1 to A2	0.00	-0.50	0.50	0.00 small
	A2 to A3	0.69	0.08	1.3	0.8 large
	A2 to A4	0.93	0.32	1.54	1 large

Table 5: Mean difference, 95% confidence intervals (CIs) and Cohen's d effect sizes (ES) for the lumbar multifidus (LM) muscle cross sectional area (CSA) outcome

DISCUSSION

The aim of this study was to provide a proof-of-concept evaluation of the efficacy of a 6-week supervised intervention using the FRED in people with chronic non-specific LBP in terms of self-reported function, pain and LM muscle CSA.

The current study did not find a clinically significant reduction in pain intensity following the intervention period (NPRS MCID = 2). The pain reduction reported by a number of participants in the control period *before* the FRED, is consistent with the observed flaring nature of LBP with most individuals experiencing fluctuations of symptoms over time (Costa, Ferreira, Setchell, Makovey, Dekroo, Downie, et al., 2019; Dunn, Campbell & Jordan, 2013). In this present study, it may also stem from reassurance by the advanced practitioner physiotherapist (DD) that their symptoms did not stem from a serious pathology. This may have led to a reduction in pain simply by reducing their pain-related anxiety (Butler, 2000).

The current study identified a wide range of responses of pain to FRED exercise. One participant reported a complete resolution of symptoms following the intervention, whereas three participants reported a mild increase in pain following the intervention period. The absence of significant decrease in pain following the intervention period may be explained by

the reports of several participants that they had returned to activities they had not done for years - this is apparent from the PSFS scores of these participants which all started at zero (i.e. activities that the participants had given up completely due to their pain). This included engaging in heavy lifting, strenuous hill walking and otherwise increasing their physical exercise in duration and/or level of physical effort. This is to be considered an important improvement in these participants, as in many people with chronic LBP the fear of pain and resulting avoidance of movement and activities that may trigger the pain becomes a bigger problem than the pain itself (Crombez, Vlaeyen, Heuts, & Lysens, 1999; Vlaeyen & Linton, 2000).

Importantly, informal conversations with participants revealed that, although pain *intensity* was mostly unchanged, several participants experienced *faster resolution* of symptoms following the FRED exercise intervention. This suggests that future studies investigating people with (chronic) LBP should examine both pain intensity and duration so that this important aspect can be analysed appropriately. During the intervention period only one exercise session (out of a possible 234) was halted due to an increase in LBP.

Improvements in self-reported function were made in all activity types measured, with an average increase of 4.3±1.2 points. This is more than twice the MCID for this scale for chronic LBP (Horn et al., 2012). Importantly, participants had been asked to choose activities for the PSFS which had direct relevance to and impact on their working lives and leisure activities. This improvement in function is particularly encouraging, bearing in mind the mean chronicity of LBP of 14 ± 13 years in this study population.

This finding parallels the published findings of functional improvements following MCT interventions (Macedo et al., 2012; Saner et al., 2016). The functional improvements found in this study appeared to be larger than those reported by Macedo et al (2012) and Saner et al. (2016). However, this may be, because the current study specifically identified activities which participants were *unable* to perform at A1. In some previous studies participants started with a higher PSFS score at baseline, which would have reduced the potential for improvement

over the duration of the study in comparison to this study. Importantly, Macedo et al.'s (2012) and Saner et al.'s (2016) studies both were RCTs involving 172 and 106 participants, respectively, and any direct comparison between the present uncontrolled study and previous data needs to be considered very cautiously. Other differences in methodology, including the length of the intervention period, the length of individual treatment sessions, total number of exercise sessions, total exercise time and follow-up periods, also preclude a direct comparison of improvement in PSFS scores between studies.

The large effect size of the increase in LM muscle CSA (A2 to A3: d = 1.00, and from A2 to A4: d = 1.04) which was maintained at 6-week follow-up constitutes an important objectively measurable change following the FRED exercise intervention. It is of relevance in relation to people with LBP, as well as in other conditions where atrophy of the paraspinal muscles has been observed, such as following long-term bedrest and spaceflight (Hides et al., 2008; Lambrecht et al., 2017). Although the present study was not designed to address the mechanism for change in muscle size, it is important to consider this with respect to existing data. Our observation of substantial muscle gain despite modest activation might appear to contrast that of the study of Danneels et al. (2001b), that showed that addition of a strengthening programme to motor control training involving gentle specific activation of the back muscles alone was required to increase multifidus CSA. Key elements of the strengthening programme implemented in that study were eccentric activation and static holding under load. Although FRED exercise involved modest muscle activation, the upright posture and demand to control spine position during leg movement on a relatively unstable platform, may have induced sufficient demand to induce hypertrophy. Our previous work (Weber et al., 2017) shows that during FRED exercise LM muscle contraction is more sustained (i.e., tonic) than treadmill walking, and is likely to involve sustained activation with oscillation between concentric and eccentric contraction.

A further consideration is that the effects of training on muscle mass might not depend only on the exposure to training during the FRED exercise programme. It is important to note

that muscle changes in LBP do not only relate to effects at the level of muscle, there is an extensive literature of changes in neuromuscular control (Strutton, Theodorou, Catley, McGregor, & Davey, 2005; Tsao, Galea, & Hodges, 2008). It is plausible that exposure to the FRED exercise may have modified muscle activation and integration of enhanced recruitment into functional activity, thus effectively increasing the exposure of the muscle to exercise/loading. Transfer of improved muscle activation to other tasks, such as walking, has been reported for some motor control interventions for back muscles (Tsao & Hodges, 2007). This would also explain the maintenance of LM muscle CSA at 6-week follow-up and concurs with other observations for abdominal muscles with motor control interventions (Tsao & Hodges, 2008). This observation is important to consider as the programme that was implemented involves less load and dosage than that generally advocated for muscle hypertrophy. Future analyses should consider the impact of exposure to FRED exercise on the activation of the back muscles in function.

Limitations

This proof-of-concept study involved a relatively small sample (N=13), did not use a control group, and did not test statistical significance. This study also did not investigate the effectiveness of FRED training relative to other rehabilitation approaches for patients with chronic LBP. Although the rater was blinded to both participant number and time point at which each LM CSA image was taken in order to limit bias, the same physiotherapist (KL) supervised the exercise and recorded the LM CSA images. This might have introduced bias.

CONCLUSION

This proof-of-concept study was the first to examine FRED exercise as an intervention for individuals with chronic LBP. It involved two patient-reported outcome measures (PSFS and NPRS) and ultrasound imaging of lumbar multifidus muscle CSA. The study provides preliminary evidence that a 6-week programme of FRED exercise can improve self-reported

function by more than twice the MCID in a range of physical activities. This was maintained at six and 15 weeks post-intervention. The LM CSA inceased with a large effect size following the FRED intervention which was maintained at six weeks post-intervention (not examined at 15 weeks post-intervention). In view of participants' resumption of activities following the intervention which they had given up due to their LBP and the chronicity of their symptoms (14 ± 13 years), the absence of a reduction in pain might not reflect a negative outcome. Exercise using the Functional Re-adaptive Exercise Device may constitute an effective approach in the rehabilitation of people with chronic LBP who present with a loss of physical function and LM muscle atrophy. The intervention should now be tested in an appropriately powered randomised controlled clinical trial.

Declarations of interest: none.

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